NEONATCOM Committee
Agenda

May 18, 2026, at 9:00 a.m.

Virtual

1. **Call to Order and Welcome**
2. **Roll Call**
3. **Review of Meeting Minutes**
4. **Public Comment Period**
5. **Review and Discussion**

   Guests

Alex Kline, M.D.	Division Chief for Neonatology, Inova
Amy L Kageals	Senior Director, Carilion
Andrew C. Herman, M.D.	Chair, Department of Pediatrics, Carilion
Paul B Davenport	System Senior Vice President, Carilion

   Materials

   - Redlined Neonatal Special Care Services VA Administrative Code
   - Neonatal Service Information from Surrounding States *

6. **Next Steps and Wrap Up**

   Schedule next virtual meeting date

7. **Meeting Adjournment**

***Neonatal Services and Note from Surrounding States**

2024-5-01 Children's Special Delivery Unit Findings

The D.C. State Health Planning and Development Agency (SHPDA) does not have regulations or resources specifically related to neonatal services. They recently approved a special delivery unit at Children's Hospital (please see attached). Other than the neonatal services related to the special delivery unit, the SHPDA has not reviewed any other projects specifically related to neonatal service in the last 5 years.

NICU Standards Governor Approved- W.VA

MO 580-2501 New Hospital Application

A CON is required for construction of a new hospital, which could offer neonatal services. CON does not have specific statutes or regulations for neonatal beds, but we do have a bed need calculation for pediatric beds as shown below. The MO 580-2501 New Hospital Application is checklist new hospitals are required to follow when submitting a CON application. If an existing licensed hospital is increasing beds or adding a new specialty, a CON is not required for that.

What is the unmet need according to the following population-based bed need formula using (Unmet Need = (R × P) – U), where—

P = Projected year population in the service area;

U = Number of licensed and approved beds in the service area; and

R = Community need rate of one (1) bed per population in the service area as follows:

1. Medical/surgical bed: 570
2. Pediatric bed: 8,330
3. Psychiatric bed: 2,080
4. Substance abuse/chemical dependency bed: 20,000
5. Inpatient rehabilitation bed: 9,090
6. Obstetric bed: 5,880

TN Health Facilities Commission Quality Service License Information

Currently being created; referred to their website:

TN Health Facilities Commission Quality Service License Information

Virginia Administrative Code
Article 2. Neonatal Special Care Services
12VAC5-230-940. Travel time.
Article 2

Neonatal Special Care Services

A. Intermediate level neonatal special care services should be located within 30 minutes driving time one way
Leave as is.
under normal conditions of hospitals providing general level new born services using mapping software as determined by the commissioner.
B. Specialty and subspecialty neonatal special care services should be located within 90 minutes driving time one way under normal conditions of hospitals providing general or intermediate level newborn services using mapping software as determined by the commissioner.

12VAC5-230-950. Need for new service. Leave for now; may need to add to this.

No new level of neonatal service shall be offered by a hospital unless that hospital has first obtained a COPN granting approval to provide each such level of service.

12VAC5-230-960. Intermediate level newborn services.

A. Existing intermediate level newborn services as designated in 12VAC5-410-443 should achieve 85% average annual occupancy before new intermediate level newborn services can be added to the health planning region.
B. Intermediate level newborn services as designated in 12VAC5-410-443 should contain a minimum of six bassinets.
C. No more than four bassinets for intermediate level newborn services as designated in 12VAC5-410-443 per 1,000 live births should be established in each health planning region.
May need to refine language in this section.

12VAC5-230-970. Specialty level newborn services.

A. Existing specialty level newborn services as designated in 12VAC5-410-443 should achieve 85% average annual occupancy before new specialty level newborn services can be added to the health planning region.
B. Specialty level newborn services as designated in 12VAC5-410-443 should contain a minimum of 18 bassinets.
C. No more than four bassinets for specialty level newborn services as designated in 2VAC5-410-443 per 1,000 live births should be established in each health planning region.
D. Proposals to establish specialty level services as designated in 12VAC5-410-443 shall demonstrate that service volumes of existing specialty level newborn service providers located within the travel time listed in 12VAC5-230-940 will not be significantly reduced.

12VAC5-230-980. Subspecialty level newborn services.

A. Existing subspecialty level newborn services as designated in 12VAC5-410-443 should achieve 85% average annual occupancy before new subspecialty level newborn services can be added to the health planning region.
B. Subspecialty level newborn services as designated in 12VAC5-410-443 should contain a minimum of 18

bassinets.
C. No more than four bassinets for subspecialty level newborn services as designated in 12VAC5-410-443 per 1,000 live births should be established in each health planning region.
D. Proposals to establish subspecialty level newborn services as designated in 12VAC5-410-443 shall demonstrate that service volumes of existing subspecialty level newborn providers located within the travel time listed in 12VAC5-230-940 will not be significantly reduced.

12VAC5-230-990. Neonatal services. Is there a need? AAP will solve. Will need to review.

The application shall identify the service area and the levels of service of all the hospitals to be served by the proposed service.

12VAC5-230-1000. Staffing.

All levels of neonatal special care services should be under the direction or supervision of one or more qualified physicians as described in 12VAC5-410-443.

DC | HEALTH
GOVERNMENT OF THE DISTRICT OF COLUMBIA

State Health Planning and
Development Agency

DISTRICT OF COLUMBIA
STATE HEALTH PLANNING AND DEVELOPMENT AGENCY
CERTIFICATE OF NEED REVIEW
FINDINGS IN THE MATTER OF:
CHILDREN'S NATIONAL HOSPITAL
CERTIFICATE OF NEED REGISTRATION NO. 2024-5-01

The findings contained in this document were developed in conformance with Certificate of Need ("**CON**") review criteria required by D.C. Code § 44-401 et seq. and contained in Title 22-B of the District of Columbia Municipal Regulations, Chapters 40 through 45, and reflect my assessment of the information in the project record and are consistent with the applicable considerations, standards, and criteria for CON review. These findings are based on the information contained in the CON application by Children's National Hospital ("**Children's** or "**CNH**" or the "**Applicant**") and all related documents and testimony submitted to the record, including the record related to the information gathering public hearing convened on August 27, 2024 via WebEx. The Application was reviewed by the State Health Planning and Development Agency ("**SHPDA**") and presented to the Project Review Committee ("**PRC**") and the Statewide Health Coordinating Council ("**SHCC**") on October 10, 2024 for consideration.

Consistent with 22B DCMR § 4012.1, "[w]henever a criterion or standard requires proof of a fact, the applicant shall have the burden of affirmatively proving that fact." Here, the SHPDA finds that Children's has set forth sufficient facts throughout its application to support the criteria and standards required for this project. A summary of relevant facts is provided in Section B. Review Findings and Analysis.

A. Description of Proposed Activity:

Children's National Hospital is seeking a Certificate of Need to establish a Special Delivery Unit ("**SDU**") at its Sheikh Zayed Campus, located at 111 Michigan Avenue, NW, Washington, D.C. According to the record, the SDU will cater to low-risk pregnant individuals carrying high-risk fetuses, combining neonatal and maternal care in a centralized location.

The proposed SDU will occupy 23,630 square feet on the 5th floor, directly connected to the existing Neonatal Intensive Care Unit ("**NICU**") on the 6th floor. The Applicant states that it underwent a feasibility study to evaluate three potential locations and determined that co-locating the facility with the NICU is preferred as it has access to public and staff elevators, direct connection to the NICU and sufficient floor height for the construction of a C Section/operating room with required utility infrastructure. The existing space is the self-contained delivery unit which will undergo renovation. The facility will provide comprehensive care before, during, and after delivery, ensuring immediate intervention by pediatric subspecialists if necessary. According to Children's, the SDU aims to improve access to maternal-fetal services for Washington, D.C. residents, reducing healthcare inequities. Key benefits include:

- Offering local, comprehensive maternal-fetal care.
- Providing immediate pediatric intervention at birth when needed.
- Keeping mothers and infants together during the critical neonatal period, avoiding developmental and mental health issues associated with separation.

The childbirth center at Inova Women's Hospital on the Inova Fairfax Medical Campus is not considered a SDU although it is within proximity to Inova L.J. Murphy Children's Hospital a 108-bed, Level IV NICU. The closest Special Delivery Unit is 40 miles away in Baltimore, Maryland. This distance to Baltimore may place a significant burden on families, often forcing them to travel or relocate. The proposed SDU is anticipated to reduce costly emergency transport and out-of-network expenses, while also offering access to one of the nation's top-ranked NICUs according to U.S. News & World Report. This project is not expected to negatively impact existing healthcare providers in the region but will instead fill a critical gap in specialty neonatal care.

The SDU will include the following:

- Four private Labor Delivery Recovery Postpartum ("**LDRP**") rooms;
- Two private antepartum rooms;
- One large cesarean section operating room;
- One dedicated infant resuscitation room;
- Two consultation rooms; and,
- One obstetric ultrasound room.

Architectural design is set to be completed in 2024, with construction beginning in 2025 and project completion expected in March 2027. The goal is to provide care for low-risk mothers and high-risk fetuses, ensuring the newborn receives specialized care at Children's NICU. This new unit is intended to reduce the need to travel to facilities like Inova Fairfax Hospital, Johns Hopkins University Hospital, or Children's Hospital of Philadelphia, which travel may necessitate families being separated during critical neonatal periods.

Approval of the CON will allow Children's to leverage its renowned neonatal expertise and cutting-edge maternal care. The Prenatal Pediatrics Institute, part of Children's, already conducts pioneering fetal imaging and multidisciplinary evaluations. This new initiative will consolidate care across the prenatal-neonatal continuum, ensuring the best possible outcomes for critically ill newborns in Washington, D.C.

Deliveries at the SDU will be limited to low-risk pregnant people (individuals who are free of any pregestational or gestational conditions (e.g., high blood pressure, diabetes, obesity)) referred by maternal-fetal medicine specialists, and the program will only handle cases where the fetus is at significant risk. The proposed SDU will be staffed by rotating obstetricians and anesthesiologists whose primary affiliation is with high-volume obstetric practices and these physicians will be contracted to provide services to the SDU on a rotational basis, spending the majority of their time in larger practices will be contracted to provide services to the SDU on a rotational basis, spending the majority of their time in larger practices.

Children's is an inpatient specialty hospital generally serving pediatric patients (birth to 21 years) that operates 323-licensed bed and serves over 15,000 inpatients annually. Children's also operates five health centers in Washington, D.C., and seven regional outpatient facilities. As the largest pediatric care provider in the District, it reported over $21 million to the SHPDA in uncompensated care in calendar year 2022 and serves as the regional referral center for pediatric critical care specialties. The hospital also offers research participation opportunities for families, promoting involvement in relevant studies.

The Applicant states that the new SDU will address a critical need for low-risk mothers and high-risk fetuses, a demographic currently underserved in Washington, D.C. Presently, families with high-risk pregnancies – pregnancies which are determined during the fetal period by multidisciplinary evaluation in the Children's Prenatal Pediatrics Institute to be at significant risk for complicated transition to postnatal life and secondary injury or demise – that seek care at a specialty delivery unit must travel to Virginia, Baltimore or Philadelphia.

The Applicant maintains that the capital expenditure associated with the proposed project is THIRTY-EIGHT MILLION EIGHT HUNDRED SIXTY THOUSAND FOUR HUNDRED SIXTEEN DOLLARS (**$38,860,416**) and will become operational in March 2027.

B. Review Findings and Analysis

1. Need for the Proposed Project:

The Applicant states that Children's National Hospital is the largest Level IV Neonatal Intensive Care Unit in Washington, D.C. The nearest facilities able to perform similar services are in Baltimore, Maryland; Philadelphia, Pennsylvania; and Fairfax, Virginia which may cause families to travel outside the District for the delivery and ongoing care of critically ill newborns.

This gap in care is particularly concerning for individuals with complex pregnancies—such as those expecting babies with congenital malformations or other significant health risks—who lack access to essential services close to home. Washington, D.C., however, does have three facilities offering labor and delivery services near a Level III NICU and MedStar Georgetown University Hospital provides labor and delivery services near a Level IV NICU. The American Academy of Pediatrics ("**AAP**") establishes the levels of NICU (see Table 1).

Table 1. American Academy of Pediatrics Definitions, Capabilities, and Provider Types: Neonatal Levels of Care

Level of Care	Capabilities	Provider Types*
Level I Well newborn nursery	• Provide neonatal resuscitation at every delivery	Pediatricians, family physicians, nurse practitioners, and other advanced practice registered nurses
	• Evaluate and provide postnatal care to stable term newborn infants	
	• Stabilize and provide care for infants born 35–37 wk gestation who remain physiologically stable	
	• Stabilize newborn infants who are ill and those born at <35 wk gestation until transfer to a higher level of care	
Level II Special care nursery	Level I capabilities plus:	Level I health care providers plus: Pediatric hospitalists, neonatologist, and neonatal nurse practitioners.
	• Provide care for infants born ≥32 wk gestation and weighing ≥1500 g who have physiologic immaturity or who are moderately ill with problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an urgent basis	
	• Provide care for infants convalescing after intensive care	
	• Provide mechanical ventilation for brief duration (<24 h) or continuous positive airway pressure or both	
	• Stabilize infants born before 32 wk gestation and weighing less than 1500 g until transfer to a neonatal intensive care facility	
Level III NICU	Level II capabilities plus:	Level II health care providers plus: Pediatric medical subspecialists[a], *pediatric anesthesiologists*[a], pediatric surgeons, and pediatric ophthalmologists[a].
	• Provide sustained life support	
	• Provide comprehensive care for infants born <32 wks gestation and weighing <1500 g and infants born at all gestational ages and birth weights with critical illness	
	• Provide prompt and readily available access to a full range of pediatric medical subspecialists, pediatric surgical specialists, pediatric anesthesiologists, and pediatric ophthalmologists	
	• Provide a full range of respiratory support that may include conventional and/or high-frequency ventilation and inhaled nitric oxide	
	• Perform advanced imaging, with interpretation on an urgent basis, including computed tomography, MRI, and echocardiography	
Level IV Regional NICU	Level III capabilities plus:	Level III health care providers plus: Pediatric surgical subspecialists
	• Located within an institution with the capability to provide surgical repair of complex congenital or acquired conditions	
	• Maintain a full range of pediatric medical subspecialists, pediatric surgical subspecialists, and pediatric anesthesiologists at the site	
	• Facilitate transport and provide outreach education	

Source: American Academy of Pediatrics
https://www.cdph.ca.gov/Programs/CHCQ/LCP/CDPH%20Document%20Library/AFL-19-37-Attachment5.pdf
accessed September 2024.

The infants who would be served by the proposed Special Delivery Unit are those diagnosed during pregnancy with conditions that critically impair their ability to survive independently after birth. These babies are anticipated to require immediate, specialized resuscitation and support from an expert pediatric-surgical team equipped with advanced life-support technologies.

Without such care, they face a high risk of serious complications, including brain injury or death. Currently, no hospital in D.C. can directly deliver high-risk babies into the hands of a specialized pediatric-surgical and NICU team. According to Children's, infants born with these high-risk conditions at an existing acute care hospital in the District of Columbia require transfer to Children's for surgery and further treatment.

The target population of critically ill neonates and low-risk mothers will be referred directly to the Prenatal Pediatrics program at Children's. There will not be self-referrals; marketing efforts will target obstetricians and maternal-fetal medicine providers so that they are aware of this service. The Applicant states that District-wide awareness of the program will be established through professional collaboratives as well.

The American College of Obstetricians and Gynecologists ("**ACOG**") defines a low-risk pregnancy as a clinical scenario for which there is not clear demonstrable benefit for a medical intervention. The Applicant further states that *low-risk pregnant individuals* are defined for the purposes of this application as individuals who are free of any pregestational or gestational conditions (e.g., high blood pressure, diabetes, obesity) that would place them at increased risk for complications that would threaten the health or life of the birthing patient. The Applicant defines *high-risk neonates* as those who were determined during the fetal period by multidisciplinary evaluation in the Prenatal Pediatrics Institute to be at significant risk for complicated transition to postnatal life and secondary injury or demise. The Prenatal Pediatrics Institute at Children's is an academic medical center that diagnoses, treats, and supports neonates and their parents. The Applicant states that the Institute uses research, expertise, coordinated and advanced care, personalized treatment plans, and more. The Applicant further states that patients who would be delivered in the SDU include high-risk neonates with diagnoses such as:

- Congenital heart diseases:
    - Hypoplastic Left Heart Syndrome (with restrictive foramen ovale)
    - Total anomalous venous return (obstructed)
    - D-transposition of the great arteries (with restrictive foramen ovale)

    - Severe tetralogy of Fallot with absent pulmonary valve
    - Severe Ebstein's anomaly
    - Complete heart block
    - Ectopia Cordis
- Bowel Obstruction/Atresia
- Congenital Diaphragmatic Hernia
- Obstructive Airway Lesions
- Major Abdominal Wall Defects (i.e., Gastroschisis, Large omphaloceles)

The Applicant states that its priority population currently receives care along one of two distinct pathways. Some pregnant individuals deliver their babies at a local hospital, the newborn then requires immediate transfer to Children's for specialized treatment (*see* Table 2). The Applicant states that the separation of the birthing parent and baby disrupts continuity of care and the crucial early bonding period. The second option is that families may choose to deliver at more distant facilities with delivery capability. This choice allows them to ensure that their babies receive continuous care at the same hospital from delivery through post-delivery treatment. The creation of the Special Delivery Unit in Washington, D.C. aims to address these challenges for families in the District and surrounding areas. The District also allows for Children's to request a variance from its license to address critical conditions, however, the records from the Department of Health demonstrate that a variance has not been requested in more than 4 years.

Table 2. Total Coordinated Delivery Transfers to Children's National Hospital 2020-2024

Fiscal Year	**Cardiac Intensive Care Unit**	**Neonatal Intensive Care Unit**	**Fiscal Year Total**
2020	26	40	66
2021	37	54	91
2022	25	41	66
2023	17	47	64
2024	31	41	72
Total	**136**	**223**	**359**

Source: Data provided to the SHPDA by the Applicant.

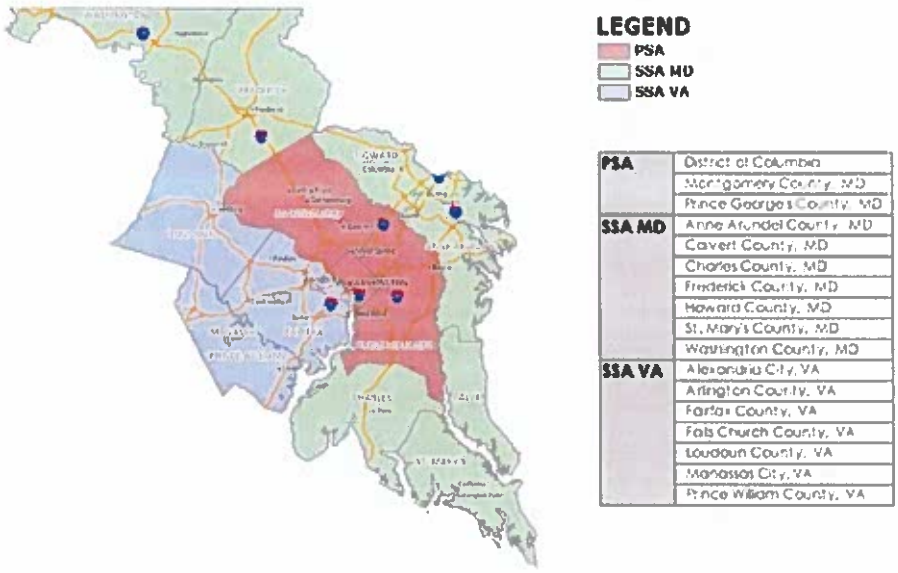
The Applicant states that the current situation, without a special delivery unit in Washington, D.C., raises significant concerns. For example, if D.C. families with high-risk pregnancies are required to deliver at a distant center, their pregnancies must be managed by an out-of-state obstetric team. In the case of unexpected premature labor, which is more common in high-risk pregnancies, these families may not be able to reach the remote facility in time. This could lead to an emergency delivery at a local hospital that is unfamiliar with the pregnancy and lacks the critical care needed for the neonate who may need to be transported to Children's. Any delay, as well as the suboptimal conditions during ambulance transport, may result in irreversible injury or death. Furthermore, the parent would be separated from her unstable child during critical interventions and decisions.

The Applicant states that the proposed Special Delivery Unit at Children's would resolve these issues by integrating obstetric care, delivery planning, and postnatal interventions in one location. This would allow the birthing patient and baby to remain together during the critical neonatal period, providing essential continuity of care.

The Applicant argues that establishing the SDU at CNH will reduce these risks by enabling critically ill newborns to be delivered directly into the care of expert pediatric and neonatal specialists, eliminating the need for transfer between facilities. The SDU will be located on the same floor as the Level IV NICU, ensuring that newborns receive immediate, specialized care at birth. This direct access is vital for high-risk pregnancies, particularly for infants diagnosed prenatally with conditions such as complex congenital heart disease, neurological abnormalities, or other severe health issues requiring immediate resuscitation or surgery. In 2020, CNH's NICU treated 640 critically ill newborns from its primary service area. The Applicant projects that in the first year, approximately 5–6 patients per month would benefit from delivery in the SDU, with an estimated 150–200 birthing parents and infants benefitting annually once the unit is fully operational.

According to data provided by the Applicant, 87% of the NICU's patients from 2020 to 2023 were from the hospital's primary service area, which includes Washington, D.C., and surrounding regions in Maryland and Virginia (*see* Figure 1). The proposed SDU will primarily serve these families, offering them the opportunity to deliver their babies close to home with support from their local community, avoiding the disruption and stress of traveling out of state. The patient base for the SDU as illustrated in Figure 1will encompass the service area of Children's, described in the CON application, covering a wide geographic area with their primary and secondary service areas (*see* Figure 1) with an estimated 80,000 births annually.

Figure 1. Children's National Hospital Primary and Secondary Service Areas



Source: Figure provided to the SHPDA by the Applicant. (PSA: Primary Service Area; SSA: Secondary Service Area)

In 2023, the District of Columbia's infant mortality rate was 5.45 deaths per 1,000 live births. Non-Hispanic Black infants were 3.5 times more likely to die compared to non-Hispanic white infants. Despite overall lower infant mortality rates, D.C. still faces significant gaps in specialized care for high-risk newborns, which may exacerbate existing disparities. Expectant parents carrying babies with complex medical conditions currently face difficult choices: either

travel outside the District for specialized care or deliver in an existing D.C. facility with their infants potentially needing to be transferred to a separate facility for intensive care.

The D.C. Health Perinatal Health and Infant Mortality Report emphasizes that every newborn should receive high-quality neonatal care in both hospital and outpatient settings. It also stresses that all healthcare facilities providing maternal and infant care must have the tools and resources to implement evidence-based care, care coordination, and quality improvement activities.

SHPDA concurs that the proposed Special Delivery Unit addresses a service that currently does not exist in the District of Columbia and agrees that the proposed project will increase access to services for low-risk pregnant individuals for whom the fetal period is at high risk for a complicated transition to postnatal life and secondary injury or demise.

Thus, Children's has set forth sufficient facts to support the criteria and standards of Need.

2. Accessibility:

The Applicant states that, as a trusted healthcare provider serving the District of Columbia and its metropolitan region, Children's has long worked to ensure that its services are available to all families, regardless of socioeconomic status or geographic location. The proposed SDU will extend this commitment by being situated on the hospital's main campus at 111 Michigan Avenue NW, which is centrally located and accessible by various modes of transportation.

The Applicant states that the proposed project will offer access to intensive care services for critically ill babies transitioning from the Special Delivery Unit to the adjacent NICU. The NICU provides care from neonatal intensive care specialists 24 hours a day, seven days a week. The Special Delivery Unit will operate in a phased approach initially offering only deliveries by Cesarean section 24 hours a day, Monday through Friday, with closure on weekends. The SDU will operate 24 hours a day, seven days a week in the sequential phases. The Applicant has determined that a phased approach to opening the Special Delivery Unit will work best and stated that it will perform deliveries by way of a three phased approach based on the

programmatic development and continued needs assessment. The Applicant has stated that its planned phases will occur accordingly:

- **Phase 1**: Deliveries will occur by scheduled Cesarean section (C-section) only with anesthesia provided by an adult trained anesthesiologist from CNH or from adult partnering hospital performed two days per week and to allow for post C-section recovery and closure of the SDU on weekends. Off cycle deliveries will occur at the primary delivery center with rapid transport of the neonate to Children's.

- **Phase 2**: Phase 2 will offer the same services as Phase 1 with the inclusion of scheduled inductions. All staffing will be adjusted to account for this transition. The SDU will operate under 24-hour anesthesia coverage until deliveries are complete. Children's will continue to collaborate with adult partnering hospitals.

- **Phase 3**: In Phase 3, Children's will transition to 24/7 coverage for obstetrics, anesthesia and nursing offering spontaneous off-cycle labor and delivery.

The Applicant has stated that the process of identifying pregnancies that may require critical care delivery at Children's proposed SDU will be as follows:

- Pregnant individuals referred to the Prenatal Pediatrics Institute ("**PPI**") by regional obstetricians and maternal-fetal medicine specialists because of concerns regarding fetal well-being undergo multidisciplinary evaluation.
- When it is determined that the fetal condition will require rapid intervention soon after birth to optimize the infant's transition from prenatal to neonatal life and to avoid the risk of neonatal demise or irreversible injury, these recommendations will be communicated to the referring maternal caretaker.
- A maternal-fetal medicine consultation will be requested to confirm that the birthing patient is at low risk for other pregnancy and delivery complications.
- In collaboration with the referring caretaker, the PPI team will develop a detailed delivery plan and assemble a multidisciplinary team (including specialists caring for the birthing

patient as well as those required to respond rapidly and effectively to the newborn critical care).

- In many complex cases, the entire team will undergo simulation training sessions to ensure safe and effective coordination of care at the time of birth.
- Once stabilized, the newborn would be transferred to the adjacent NICU for further evaluation and treatment, while the birthing patient is moved to postnatal care, provided close to her infant and care providers.

The hospital is served by multiple Metrobus lines, including the H-1, H-2, and H-4 routes, which stop directly in front of the main campus. Additionally, the Brookland-Catholic University Metro station, located 1.4 miles away, provides access to the District's Metrorail Red Line, making the hospital easily reachable for those using public transit. A free shuttle is available from the Main campus to several Metro stations. For families traveling by car, the hospital offers parking and valet services, ensuring that patients can arrive at the SDU without added stress or expense.

Accessibility also extends beyond transportation. Children's states that it is committed to removing financial barriers that might prevent families from accessing the care they need. Children's provides a large amount of uncompensated care in Washington, D.C., and the Applicant states that the hospital has a long history of serving families who are underinsured or uninsured. Over 50% of existing NICU patients are Medicaid beneficiaries, and the hospital ensures that no child is ever turned away due to their family's inability to pay.

This financial accessibility will be a cornerstone of the SDU's operations. Expectant parents with qualifying conditions will be able to deliver their babies at the SDU without fear of financial hardship. Children's states it is dedicated to serving all families, ensuring that every newborn receives the care they need, regardless of their financial situation.

The Applicant states that for families whose primary language is one other than English, Children's offers translation services in person or telephonically. The primary language of patients needing translation services (including sign language) is identified in Children's

electronic medical record. Qualified interpreters are available for patients and families at no cost, on-site at the Main Campus, seven days a week, 24 hours per day. The most encountered translation need is Spanish language translation. The Applicant stated that language access services will similarly be provided to special delivery unit patients and their families.

By situating the SDU in a central, accessible location and eliminating financial barriers to care, Children's maintains that families, regardless of their background or circumstances, can access life-saving care for their newborns. The SHPDA encourages the Applicant to further consider its phased approach to becoming operational, as the myriad variables within labor and delivery processes will make it very difficult to maintain a consistent and appropriate schedule. Otherwise, SHPDA finds the CON application is uncontested as it relates to accessibility and consistent with the criteria and standards set forth in District law and the Health Systems Plan (2017).

Accordingly, Children's has set forth sufficient facts to support the criteria and standards necessary for Accessibility.

3. Quality of Care:

The Applicant states that Children's, and its NICU, are consistently ranked among the best in the country. The hospital's Level IV NICU, which provides the highest level of care available for newborns, has been ranked as the #2 neonatal program in the United States by U.S. News & World Report. The establishment of the SDU will extend this legacy of excellence, offering parents and newborns access to the same world-class care that has earned Children's its reputation as a leader in pediatric medicine.

The SDU will be equipped with state-of-the-art medical technology, ensuring that it can meet the complex needs of critically ill newborns. The unit will include four private Labor, Delivery, Recovery, and Postpartum (LDRP) rooms, two antepartum rooms, a large cesarean section operating room, a dedicated neonatal resuscitation room, and two consulting rooms. This

comprehensive suite of facilities will allow the SDU to provide high-quality care for both birthing patients and newborns in one integrated space. One of the key features of the SDU will be its proximity to the hospital's NICU, which is home to a team of highly specialized neonatal experts. These specialists, who include pediatric surgeons, neonatologists, and subspecialists in areas such as neurology and cardiology, will be available 24/7 to provide immediate care for newborns. The Applicant states that this access to expert care will significantly improve outcomes for high-risk infants, many of whom require complex interventions in the moments following birth.

The Applicant states that Children's leadership relevant to the SDU and NICU is highly qualified and experienced. The SDU will be staffed by an experienced team of obstetricians who will rotate through the SDU program but will spend most of their time in an active high-volume obstetric practice. In this manner they will maintain their obstetric skills including the evaluation and management of complicated deliveries. Adult-trained anesthesiologists will be part of the team on a rotational basis, again spending most of their time in high-volume practices. Additionally, the Applicant states it will plan to run regular training sessions in the Children's Simulation Center at least monthly or more as needed. Team readiness in case of perinatal emergencies will be maintained through quarterly drills in the Children's Simulation Center, a state-of-the-art facility where multidisciplinary teams such as the proposed SDU team train in the essential principles of coordinated teamwork and communication in emergency situations to ensure the highest standards of patient safety. Holistically, all Children's physicians and staff participate in mandatory orientation and ongoing training to ensure delivery of the highest quality and safest clinical care and the best patient experience. This process includes regular training on the following topics:

- Regulatory compliance, including patient privacy, data security, and mandatory reporting;
- Patient safety and infection control, including TJC National Patient Safety Goals, hand hygiene, and blood borne pathogens;

- Workplace safety, including emergency operations, electrical/fire safety, hazardous chemical disposal, and infectious waste management/decontamination;
- Patient service, including service excellence and patient communication; and
- Knowledge about HIV/AIDS care as well as care for members in the lesbian, gay, bisexual, queer, and transgender ("LGBTQ") community.

Children's has acquired status through Centers for Medicare & Medicaid (CMS) and is accredited by The Joint Commission to provide care for patients and their families. The hospital is licensed by D.C. Health and operates consistent with District laws. These agencies conduct regular surveys to assess the hospital's compliance with the Joint Commission standards and CMS condition of participation.

Children's states it is also committed to continuous improvement in the quality of care it provides. The hospital has a comprehensive quality improvement plan in place, which includes regular staff training, simulation drills, and multidisciplinary teamwork. The SDU team will participate in these ongoing efforts, ensuring that they are prepared to handle perinatal emergencies and deliver the highest standard of care in every situation. Additionally, Children's has been designated as a Magnet hospital since 2010. Magnet status is the highest national and international recognition of an organization's professional nurses. This pediatric academic health system offers expert care through a convenient, community-based primary care network and specialty outpatient centers in the D.C. metropolitan area, including the Maryland and Northern Virginia suburbs.

Based on the above information, the SHPDA finds the record is consistent with the criteria and standards of Quality of Care.

4. Continuity of Care:

The Applicant states that continuity of care is essential when it comes to delivering critically ill newborns. In high-risk pregnancies, seamless coordination between maternal and neonatal teams is crucial to ensure that both the birthing patient and newborn receive the best possible care. The

proposed SDU at Children's is designed to provide precisely this level of coordinated care, bridging the gap between obstetric and neonatal services.

According to the Applicant, birthing patients expecting critically ill newborns may face fragmented care. They may deliver their baby at one hospital, only to have the newborn immediately transported—sometimes by ambulance or air—to another facility for neonatal care. The Applicant maintains that this separation of services not only delays life-saving interventions but also places undue stress on the family, who are forced to navigate two separate healthcare systems at once.

By contrast, the SDU at Children's will integrate these services under one roof. Expectant parents will deliver their babies in a unit located directly adjacent to the hospital's Level IV NICU and ensuring that newborns receive immediate care from the same team that has been managing their care throughout the pregnancy. This physical proximity between the delivery room and the NICU is critical for infants who require resuscitation or other life-saving interventions at birth.

The SDU will also work closely with Children's Prenatal Pediatrics Institute. This multidisciplinary institute brings together over 25 pediatric subspecialists who collaborate on complex cases, ensuring that every pregnancy is carefully monitored and managed. Individuals whose babies are diagnosed with conditions that require critical care intervention will be referred to the SDU through this program, allowing for a seamless transition from prenatal care to delivery and postnatal treatment.

In addition to providing immediate neonatal care, the SDU will ensure that parents and newborns remain close to each other throughout their hospital stay. Unlike the current system, in which newborns are often transferred to separate NICUs while the birthing patient recovers at a separate hospital, the SDU will allow families to stay together. Birthing patients will be cared for in the same facility as their newborns, reducing the emotional strain that comes from separation and enabling them to participate fully in their baby's care.

The Applicant states that Children's uses a unified enterprise electronic health record ("**EHR**") system produced by Oracle Health, formerly Cerner. The Applicant states it has used this EHR for over a decade, making historical documentation available electronically alongside current records at the point of care. Within the EHR, the Applicant offers physician, nurse, and allied health professional documentation, comprehensive ordering for inpatient and ambulatory electronic prescriptions, laboratory and radiology studies, and surgical procedures. Clinical, operational, and business processes are integrated in the EHR, including patient care across emergency, hospital, perioperative, ambulatory specialty, primary care, and post-acute rehabilitation settings, as well as patient registration, scheduling, communication, and billing activities. The Applicant further states that Children's participates in multiple local, regional, and national health information exchanges ("**HIE**") that allow the electronic transmission of protected medical records between hospitals and physician practices that are external to Children's, such as CRISP (Chesapeake Regional Information System for Our Patients), a regional HIE connecting all hospitals in Maryland, Washington, D.C., and additional states, as well as CommonWell, a national HIE that permits exchange of information between health systems using both Cerner and Epic systems.

Based on the above, SHPDA finds the application is consistent with the criteria and standards for Continuity of Care.

5. Acceptability:

Children's states that its core values of compassion, commitment, and connection drive its focus on ensuring that each patient and family member is treated with the utmost respect throughout their time at a Children's facility or under the care of a Children's provider. The Applicant states that at the core of Children's values is its commitment to patient-centered care. The hospital has a demonstrated history of ensuring that every patient's rights, dignity, and cultural needs are respected. The Applicant states that the establishment of the SDU will be no different, providing a welcoming and compassionate environment for birthing patients and their newborns during one of the most vulnerable times in their lives.

The SDU will serve a diverse population, including families from various racial, cultural, and socioeconomic backgrounds. Children's has a robust framework for ensuring that care is both culturally competent and accessible to all patients. For families whose primary language is not English, the hospital offers translation services at no cost, ensuring that every family can fully understand their care plan and communicate effectively with their medical team. Spanish is the most frequently requested language for interpretation services, but the hospital also offers support in many other languages, including sign language.

In addition to language support, all staff at Children's receive ongoing training in cultural sensitivity and diversity. This training ensures that the SDU's care teams are prepared to meet the unique needs of every family they serve, regardless of their cultural or religious background. The hospital's commitment to inclusivity is reflected in its policies, which explicitly prohibit discrimination based on race, religion, national origin, gender identity, or any other characteristic.

Birthing patients will be provided with private labor, delivery, recovery, and postpartum (LDRP) rooms, ensuring that they have the privacy and comfort they need during their stay. The unit will also include dedicated spaces for family members, allowing loved ones to stay close and support one another during this critical time.

This focus on patient-centered care will ensure that every family's experience at the SDU is as positive as possible. By prioritizing the needs, rights, and preferences of its patients, the Applicant states that it will create a unit where families feel safe, supported, and empowered to take an active role in their care.

The Applicant has informed multiple Advisory Neighborhood Commissioners regarding the proposed project and the SHPDA received a letter from ANC commission 5E in support of the project. The SHPDA received additional letters from MedStar Washington Hospital Center President, Dr. Gregory Argyros, MD, MACP, FCCP, and Howard University College of Medicine Dean, Dr. Andrea Hayes Dixon, MD, FACS, FAAP, in support of the project. The

SHPDA received written and oral comments from Howard University Hospital Administrators and affected members of the public which raised concerns about the proposed project. The SHPDA reviewed those concerns and found that the Applicant has addressed these concerns in their application and in follow up submissions. Additionally, the Applicant provided copies of its Patient Bill of Rights, grievance policies, and privacy and disclosure policies to the SHPDA.

After reviewing the record, SPDA finds the application is consistent with the standards and criteria of Acceptability.

6. Financial Feasibility:

The Applicant maintains the capital expenditure associated with the proposed project is THIRTY-EIGHT MILLION EIGHT HUNDRED SIXTY THOUSAND FOUR HUNDRED SIXTEEN DOLLARS (**$38,860,416**) and will become operational in March 2027. The Applicant further states that the proposed SDU is a financially viable project and will provide long-term benefits for both families and the healthcare system. The hospital's financial projections indicate that the SDU will be self-sustaining, with an expected annual capacity of 50 to 170 deliveries once the unit is fully operational. The Applicant has stated that the SDU will generate enough revenue to cover its operating costs while continuing to fulfill Children's mission of providing care to all families, regardless of their financial circumstances.

The Applicant states the SDU will contribute to cost savings for families and the healthcare system by enabling District families to deliver their babies in Washington, D.C., rather than traveling out of state for care and the SDU will eliminate the need for out-of-network services and emergency transportation. Currently, families who require these deliveries may face high transportation costs if their newborns require emergency transfers to hospitals outside of the District, particularly if the birthing parent and infant want to be in the same facility.

Children's is also committed to maintaining its long-standing tradition of providing uncompensated care to families in need. Over 50% of NICU patients are covered by Medicaid,

and the hospital ensures that no family is ever denied care due to financial hardship. This commitment will continue in the SDU, where families will receive the care they need regardless of their ability to pay.

The Applicant has provided information detailing the sources and amounts of funding for the proposed project including financial statements that show the facility should generate more revenues than expenses. Children's has submitted a projected manpower budget specifying the personnel required for the staffing of the proposed project.

The Applicant has stated that its provision of services is in accordance with the uncompensated care obligation under D.C. Official Code § 44-405(a).

Based on the information presented in the record, SHPDA has determined the Applicant is consistent with the criteria and standards for Financial Feasibility.

C. **Compliance with Uncompensated Care Requirements:**

Children's National Hospital has written policies governing the provision of services without charge for indigent patients in accordance with the uncompensated care obligation under D.C. Official Code § 44-405(a). Thus, the Certificate of Need is contingent on the Applicants adherence to District laws including the following:

- The requirements set forth in DC Official Code § 44-405 and submit data related to the annual level of uncompensated care provided. Additionally, Children's shall report all amounts charged to a third-party payor and all amounts "uncollectible from the insurance company or patient" separately.

- The requirements set forth in Section 4405 of Title 22-B of the District of Columbia Municipal Regulations and to annually publish in a newspaper of general circulation the uncompensated care obligation for its facility or service, to conspicuously post in its facility a notice of the availability of uncompensated care and to provide written notice to each person seeking its services of the availability of uncompensated care before

providing services, except where the emergency nature of the services makes prior notice impractical.

D. Conclusion:

After reviewing the record, SHPDA finds the Applicant has met its burden and demonstrates that the establishment of a Special Delivery Unit by Children's National Hospital will support maternal and child health outcomes in Washington, D.C. The establishment of a SDU is a response to a healthcare need in the District aimed at improving maternal and neonatal care. By offering better access to neonatal services in the same location where labor and delivery occur, Children's aims to reduce poor outcomes for high-risk fetuses transitioning to post-natal life and ensure that such care is available to all families. The SDU seeks to improve outcomes and address healthcare inequities in the region, especially as it relates to neonatal morbidity and mortality.

The D.C. Health Perinatal Health and Infant Mortality Report highlights the need for every newborn to receive quality care in both hospital and outpatient settings. It also calls for healthcare facilities to be equipped with the necessary resources to provide evidence-based care, coordination, and quality improvement.

During consultations with medical and subject matter experts, there were both supporters of the project and individuals who raised thoughtful questions. SHPDA staff took these perspectives into account. After careful review, the SHPDA has determined the Applicant has sufficiently met its burden of demonstrating each criterion for this Special Delivery Unit. Thus, SHPDA agrees that the proposed project will increase access to services and will provide a novel service that is not fully available to patients in Washington, D.C.

Accordingly, CON application (CON 2024-5-01) for the establishment of a Special Delivery Unit for Low-Risk Birthing Patients and High-Risk Fetuses by Children's National Hospital at 111 Michigan Avenue NW, Washington, D.C. 20010, is **approved** at a cost not to exceed

THIRTY-EIGHT MILLION EIGHT HUNDRED SIXTY THOUSAND FOUR HUNDRED SIXTEEN DOLLARS (**$38,860,416**).

November 4, 2024
Date

Terri A. Thompson
SHPDA Director

Certificate of Need Program

NEW HOSPITAL APPLICATION

Applicant's Completeness Checklist and Table of Contents

Project Name:_____ Project No:_____

Project Description:_____

Done	Page	N/A	Description

Divider I. Application Summary:

- ☐ ☐ ☐ 1. Applicant Identification and Certification (Form MO 580-1861)
- ☐ ☐ ☐ 2. Representative Registration (From MO 580-1869)
- ☐ ☐ ☐ 3. Proposed Project budget (Form MO 580-1863) and detail sheet with documentation of costs.
- ☐ ☐ ☐ 4. Provide documentation from MO Secretary of State that the proposed owner(s) and operator(s) are registered to do business in MO.
- ☐ ☐ ☐ 5. State if the license of the proposed operator or any affiliate of the proposed operator has been revoked within the previous five (5) years.
- ☐ ☐ ☐ 6. If the license of the proposed operator or any affiliate of the proposed operator has been revoked within the previous 5 years, provide the name and address of the facility whose license was revoked.
- ☐ ☐ ☐ 7. State if the Medicare and/or Medicaid certification of any facility owned or operated by the proposed operator or any affiliate of the proposed operator has been revoked within the previous 5 years.
- ☐ ☐ ☐ 8. If the Medicare and/or Medicaid certification of any facility owned or operated by the proposed operator or any affiliate of the proposed operator has been revoked within the previous 5 years, provide the name and address of the facility whose Medicare and/or Medicaid certification was revoked.

Divider II. Proposal Description:

- ☐ ☐ ☐ 1. Provide a complete detailed project description.
- ☐ ☐ ☐ 2. Provide the proposed number of licensed beds by medical specialty.
- ☐ ☐ ☐ 3. Provide a timeline of events for the project, from CON issuance through project competition.
- ☐ ☐ ☐ 4. Provide a legible city or county map showing the exact location of the proposed facility.
- ☐ ☐ ☐ 5. Provide a site plan for the proposed project.
- ☐ ☐ ☐ 6. Provide preliminary schematic drawings for the proposed project.
- ☐ ☐ ☐ 7. Provide evidence that architectural plans have been submitted to the Department of Health and Senior Services.
- ☐ ☐ ☐ 8. Provide the proposed square footage.
- ☐ ☐ ☐ 9. Document ownership of the project site or provide an option to purchase.
- ☐ ☐ ☐ 10. Define the community to be served (service area: projected population, area, rationale).
- ☐ ☐ ☐ 11. Provide utilization projections through the first three (3) **FULL** years of operation of the new beds
- ☐ ☐ ☐ 12. Identify specific community problems or unmet needs the proposal would address.
- ☐ ☐ ☐ 13. Provide the methods and assumptions used to project utilization.
- ☐ ☐ ☐ 14. Document that consumer needs and preferences have been included in planning this project and describe how consumers had an opportunity to provide input.
- ☐ ☐ ☐ 15. Provide copies of any petitions, letters of support or opposition received.
- ☐ ☐ ☐ 16. Document that providers of similar health services in the proposed service area have been notified of the application by a public notice in the local newspaper.
- ☐ ☐ ☐ 17. Document that providers of all affected facilities in the proposed 15-mile radius were addressed letters regarding the application.

Divider III. Service Specific Criteria and Standards:

- ☐ ☐ ☐ 1. Document the methodology utilized to determine the need for the proposed hospital.
- ☐ ☐ ☐ 2. Provide the most recent three (3) **FULL** years of evidence that the average occupancy of the same type(s) of beds at each other hospital in the proposed service area exceeds eighty percent (80%).
- ☐ ☐ ☐ 3. Discuss the impact the proposed hospital would have on utilization of other hospitals in the geographic service area.
- ☐ ☐ ☐ 4. Document the unmet need in the geographic service area for each type of bed being proposed according to the population-based need formula

Divider IV. Financial Feasibility Review Criteria and Standards:

- ☐ ☐ ☐ 1. Document that the proposed costs per square foot are reasonable when compared to the latest "RS Means Construction Cost data"
- ☐ ☐ ☐ 2. Document that sufficient financing is available by providing a letter from a financial institution or an auditor's statement indicating that sufficient funds are available.
- ☐ ☐ ☐ 3. Provide Service-Specific Revenues and Expenses (Form MO 580-1865) for the latest three (3) years, and projected through three (3) **FULL** years beyond project completion.
- ☐ ☐ ☐ 4. Document how patient charges are derived.
- ☐ ☐ ☐ 5. Document responsiveness to the needs of the medically indigent.

Approved by Governor
Date: 8/21/20

NEONATAL INTENSIVE CARE UNITS

I. INTRODUCTION

Due to a number of factors, including the need to establish a foundation for consistent standards of service by hospitals focused on the improvement of neonatal care, it is increasingly important to deliver neonates at "risk appropriate" facilities to improve outcomes for both mothers and their babies. Whether providing nursery care or care in a neonatal intensive care unit ("NICU"), there are national guidelines that have been developed that match hospitals' capabilities with maternal and neonatal risks.

The mission of the West Virginia Health Care Authority ("Authority") is to ensure that West Virginians have appropriate access to quality, affordable health care services while protecting consumers from unnecessary duplication of services.

Recognizing the critical need for NICU services at the appropriate level to be available for neonates, these standards address the necessary criteria which must be met to obtain a Certificate of Need ("CON") to provide NICU services in West Virginia.

II. DEFINITIONS

A. Acute Care: Inpatient hospital care provided to patients requiring immediate and continuous attention of short duration. Acute care includes, but is not limited to, medical, surgical, obstetric, pediatric, psychiatric, ICU and CCU care in a hospital.

B. Acute Care Bed: Any licensed inpatient bed dedicated to the use of patients requiring acute care.

C. Admission Rate: The number of patients entering into the hospital for acute care services per 1,000 population.

D. Average Daily Census: The average number of licensed acute care beds in the hospital that are used by inpatients.

E. Average Length of Stay: The average number of days a patient stays in the hospital.

F. Bed: A general measure of hospital size and capacity.

G. Capital Expenditure: Those expenditures as defined in W.Va. Code § 16-2D-2

including a series of expenditures exceeding the expenditure minimum and determined by the Health Care Authority to be a single capital expenditure subject to review.

H. Discharge Planning: A coordinated effort to ensure that each patient to be discharged from a health care facility has a planned program of needed continuing care and follow up that seeks optimum functioning of that patient and the earliest practicable discharge.

I. Discharge Rate: The number of patients who have received acute care services discharged per 1,000 population.

J. Inpatient: A patient who has been admitted to the hospital for an overnight stay or longer.

K. Intensive Care Unit (ICU): Care provided in a specially licensed unit set up for the purpose of providing maximum surveillance and support of vital functions and definitive therapy for patients suspected of having acute, or potentially reversible life-threatening impairment of single or multiple vital systems (pulmonary, cardiovascular, renal or nervous systems). Such a unit requires special equipment and specially trained staff.

L. Levels of Care: A system of categorizing neonatal services according to complexity and sophistication. Neonatal care is divided into four levels of care including basic, specialty, subspecialty and regional subspecialty care centers as defined in the most current edition of the *Guidelines for Perinatal Care* published by the American Academy of Pediatrics ("AAP"), the American College of Obstetricians and Gynecologists ("AGOG") and the Society for Maternal-Fetal Medicine ("SMFM").

M. Licensed Beds: The basic index of hospital capacity, consisting of the beds in each hospital which are licensed for acute care use. In the case of state-operated acute care facilities, it is the number set up and staffed.

N. Neonatal: A term used to refer to an infant less than 29 days old.

O. Neonatal Intensive Care Unit: An ICU specializing in the care of ill or premature newborn infants. NICUs provide extraordinary surveillance and support of vital functions and definitive therapy for infants having acute or potentially reversible life-threatening impairment of a vital system(s).

P. Observation Services: Services ordered by a patient's physician and provided by a hospital on the hospital's premises. These services include the use of a bed and periodic monitoring by the hospital's nursing or other staff, which are reasonable and necessary for a possible admission to the hospital as an inpatient. Observation beds are not licensed acute care beds.

Q. Observation Equivalent Days: The total observation hours divided by 24.

Observation equivalent days may be added to acute care days to demonstrate peak occupancy.

R. Occupancy Rate: The average percentage of licensed beds in a hospital or one of its units that are filled as of midnight each day. To demonstrate peak occupancy, the hospital may also document the occupancy rate at a different time of the day.

S. Peer Review: The evaluation of health professionals and their performance by their peers. This term relates to programs such as utilization review and professional review organizations.

III. CURRENT INVENTORY

The Authority will provide each applicant with a current inventory of existing NICU beds.

IV. NEED METHODOLOGY

An applicant proposing to provide NICU services must apply for a specific NICU level, i.e. NICU Level II, Level III or Level IV.

A. Only the three existing Level III NICU hospitals at the time of approval of this standard - West Virginia University Hospitals, Inc. (Morgantown), Charleston Area Medical Center Women and Children's Hospital (Charleston) and Cabell Huntington Hospital, Inc. (Huntington) - may apply for NICU Level IV without addressing the requirements of this section, unless the proposal involves adding beds to their hospital license. If the proposal adds licensed beds, Section C below must be addressed. Applications for NICU Level IV providers will be limited to these three licensed hospitals.

B. Applicants for NICU Level II and Level III must demonstrate that:

1. There is an unmet need for the proposed NICU service, that the proposed service will not have a negative impact on current providers of the service, and that the proposed service is the most cost-effective alternative;

2. It can delineate the service area by documenting the expected areas from which the facility is expected to draw patients. The applicant may submit testimony or documentation on the expected service area, based upon national data or statistics, or upon projections generally relied upon by professionals engaged in health planning or the development of health services;

3. It can document the expected number of days for the services to be provided by the facility for the population within the service area;

4. It can document the number of existing providers within the service area, as provided by the Authority, and the number of NICU days by existing providers in the service area based on the most recent uniform report(s) on file with the Authority;

5. There is an unmet need by demonstrating that the total expected number of NICU days, less the number of NICU days provided by existing providers in the service area, results in a difference that requires an addition of the NICU Level being proposed by the applicant.

6. Applicants must be an existing birthing hospital as provided below:
   a. Level II NICU applicants must be an existing provider of Level I nursery care.
   b. Level III tertiary care NICU applicants must be an existing provider of Level II NICU services.

C. If an applicant is seeking to add the NICU beds to its hospital license, as opposed to converting existing licensed beds to NICU beds, the Authority will not approve the addition of beds if, after completion of the project, the number of licensed acute care beds for the hospital is equal to or exceeds 160% of the average daily census for licensed acute beds for the last twelve (12) month period. The Authority may grant an exception to the 160% average daily census requirement if the applicant has experienced significant fluctuations in its occupancy levels and (a) the applicant is the sole hospital in a county or (b) the applicant has exceeded an 85% acute care occupancy level for two consecutive months during the past twelve (12) months. In determining the average daily census, the hospital may adjust for observation equivalent days and swing bed days. The Authority, in its discretion, may also take into consideration data submitted by the hospital to demonstrate the impact of a distinct part unit on the hospital's average daily census.

V. QUALITY

A The applicant must document that its birthing program meets the most current edition of the *Guidelines for Perinatal Care* published by the American Academy of Pediatrics ("AAP"), the American College of Obstetricians and Gynecologists ("AGOG") and the Society for Maternal-Fetal Medicine ("SMFM") for its current birthing level of care.

B. The applicant must provide a detailed plan for how it will meet the most current edition of the *Guidelines for Perinatal Care* published by the American Academy of Pediatrics ("AAP"), the American College of Obstetricians and Gynecologists ("AGOG") and the Society for Maternal-Fetal Medicine ("SMFM") for the proposed NICU level including, but not limited to, specially trained staff, equipment or other specialty services.

C. The applicant must demonstrate that the physical layout and location for the NICU is consistent with the most current edition of the *Guidelines for Perinatal Care* published by the American Academy of Pediatrics ("AAP"), the American College of Obstetricians and Gynecologists ("ACOG") and the Society for Maternal-Fetal Medicine ("SMFM").

D. Utilization review and quality assurance programs must be maintained.

E. The applicant must be accredited by The Joint Commission, Det Norske Veritas (DNV), or another accepted accreditation body.

VI. CONTINUUM OF CARE

A. The applicant must document how it currently collaborates with other birthing hospitals to coordinate maternal referrals and or transfers to ensure neonates are delivered at a "risk appropriate" facility and how it will collaborate if it moves to a higher level of birthing care.

B. The applicant must provide its current policy/procedure for interhospital transfers of neonates and its proposed policy for interhospital transfers of neonates when it begins the proposed NICU services.

C. The applicant must demonstrate that it has in place effective utilization review, quality assurance, peer review, and discharge planning processes.

D. The applicant shall ensure that it meets the criteria outlined in the current Guidelines for Perinatal Care, prior to notifying patients and the public that it provides a particular designated level of NICU care. The applicant must provide a plan for how it will ensure compliance with the criteria both initially and on an ongoing basis. This should include validation by a qualified external party.

VII. COST

Applicants shall demonstrate the financial feasibility of the proposal by providing an analysis of the cost-effectiveness of the proposed project to include:

A. A three (3) year projection of revenues and expenses for the project;

B. Evidence that sufficient capital is available to initiate and operate the proposed project;

C. Evidence that financing arrangements are reasonable and secure;

D. Documentation that all indigent persons needing the service can be served without jeopardizing the viability of the project; and,

E. That the charges and costs used in projecting financial feasibility are equitable in comparison to prevailing rates for similar services in similar hospitals.

VIII. ACCESSIBILITY

A. NICU services shall be provided based on patients' medical needs and appropriateness without regard to the source of referral or payment;

B. The applicant shall provide written policies, which are non-discriminatory in terms of race, color, creed, age, ethnicity, sex, sexual preference, financial resources, or location of residence.